

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Shite Sebastian, Gerard J. Colpas, Diane L. Ellis-Busby, Jennifer M. Havard And Mitchell C. Sanders

Application No.: 10/576,633 Group Art Unit: Not yet assigned

International Filing Date: November 3, 2004 Examiner: Not yet assigned

Confirmation No.: 4672

Title: METHODS, PEPTIDES, AND BIOSENSORS USEFUL FOR DETECTING A BROAD SPECTRUM OF BACTERIA

Date: <u>11/14/06</u>
EXPRESS MAIL LABEL NO. <u>EV 215902996 US</u>

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references B1-B15 and C1-C51 are enclosed.
- ☒ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☒ The listed references B1, B15, C25, C30 and C42 were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for references B8, B9, B11 and B13 under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☒ the enclosed English language abstract.

- ☐ Applicant requests that the following non-published pending applications be considered:  
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]  
\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]  
\_\_\_\_ U.S. Patent Application No. [     ], by [inventor(s)], filed [     ], Docket No.: [     ]

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Examiner

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Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [     ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[     ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: Nov. 14, 2006

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  <b>November 14, 2006</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3265.1010-004		APPLICATION NO. 10/576,633	
	FIRST NAMED INVENTOR Shite Sebastian		IA FILING DATE November 3, 2004	
	EXAMINER Not yet assigned		CONFIRMATION NO. 4672	GROUP Not yet assigned

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	4,242,447	12-30-1980	Findl, <i>et al.</i>
	A2	4,259,442	03-31-1981	Gayral
	A3	4,897,444	01-30-1990	Brynes, <i>et al.</i>
	A4	5,210,022	05-11-1993	Roth, <i>et al.</i>
	A5	5,236,827	08-17-1993	Sussman, <i>et al.</i>
	A6	5,330,889	07-19-1994	Monget
	A7	5,512,445	04-30-1996	Yang, <i>et al.</i>
	A8	5,518,894	05-21-1996	Berg
	A9	5,523,205	06-04-1996	Cossart, <i>et al.</i>
	A10	5,662,905	09-02-1997	Siadak, <i>et al.</i>
	A11	5,716,799	02-10-1998	Rambach
	A12	5,719,031	02-17-1998	Haugland, <i>et al.</i>
	A13	5,783,410	07-21-1998	He, <i>et al.</i>
	A14	5,804,395	09-08-1998	Schade, <i>et al.</i>
	A15	5,824,468	10-20-1998	Scherer, <i>et al.</i>
	A16	5,932,415	08-03-1999	Schubert, <i>et al.</i>
	A17	5,976,827	11-02-1999	Jeffrey, <i>et al.</i>
	A18	5,994,059	11-30-1999	Hogan, <i>et al.</i>
	A19	6,048,688	04-11-2000	Korth, <i>et al.</i>
	A20	6,051,391	04-18-2000	Schabert, <i>et al.</i>
	A21	6,207,430 B1	03-27-2001	Yaver, <i>et al.</i>
	A22	6,235,285 B1	05-22-2001	Burnham
	A23	6,284,517 B1	09-04-2001	Restaino
	A24	6,342,581 B1	01-29-2002	Rosen, <i>et al.</i>
	A25	6,380,370 B1	04-30-2002	Doucette-Stamm, <i>et al.</i>

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PTO-1449 REPRODUCED

**INFORMATION DISCLOSURE STATEMENT  
IN AN APPLICATION****November 14, 2006**

(Use several sheets if necessary)

ATTORNEY DOCKET NO.  
3265.1010-004APPLICATION NO.  
10/576,633FIRST NAMED INVENTOR  
Shite Sebastian1A FILING DATE  
November 3, 2004EXAMINER  
Not yet assignedCONFIRMATION NO.  
4672GROUP  
Not yet  
assigned**U.S. PATENT DOCUMENTS**

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**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1	WO 00/63394 A3	10-26-2000	The University of Georgia Research Foundation, Inc.		
	B2	EP 0 122 028 A1	10-17-1984	E-Y Laboratories, Inc.		
	B3	EP 0 430 608 A1	06-05-1991	E.R. Squibb and Sons, Inc.		
	B4	EP 0 428 000 A1	05-22-1991	Abbott Laboratories		
	B5	WO 91/16336	10-31-1991	Carlsberg A/S		
	B6	WO 97/28261	08-07-1997	The Regents of the University of California and Aurora Biosciences Corporation		
	B7	EP 0 864 864 A1	09-16-1998	Johnson & Johnson Medical Ltd.		
	B8	JP 11178567	07-06-1999	BML KK		X
	B9	JP2000093195	04-04-2000	Nippon Suisan Kaisha Ltd.		X
	B10	WO 00/50872 A2	08-31-2000	Cellomics, Inc.		
	B11	JP2001169799	06-26-2001	Iatron Lab		X
	B12	WO 01/59149 A2	08-16-2001	Cellomics, Inc.		
	B13	JP2001299381	10-30-2001	Iatron Lab		X
	B14	WO 02/10433A2	02-07-2002	Expressive Constructs, Inc.		
	B15	WO 03/063693A2	08-07-2003	Expressive Constructs, Inc.		

EXAMINER

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C1	Altekruse, S.F., <i>et al.</i> , "Cheese-Associated Outbreaks of Human Illness in the United States, 1973 to 1992: Sanitary Manufacturing Practices Protect Consumers," <i>J. Food Prot.</i> , 61(10): 1405-1407 (1998).	
C2	BBC News, HEALTH, "Smart bandage 'spots infection'," [online] November 5, 2001 [retrieved on 2002-01-23] Retrieved from the Internet <URL: <a href="http://news.bbc.co.uk/hi/english/health/newsid_1634000/1634639.stm">http://news.bbc.co.uk/hi/english/health/newsid_1634000/1634639.stm</a>	
C3	Braun, V. and Schmitz, G., "Excretion of a Protease by <i>Serratia Marcescens</i> ," <i>Arch. Microbiol.</i> , 124: 55-61 (1980).	
C4	Cormican, M. G., <i>et al.</i> , "Detection of Extended-Spectrum $\beta$ -Lactamase (ESBL)-Producing Strains by the Etest ESBL Screen," <i>J. Clinical Microbiology</i> 34(8): 1880-1884 (1996).	
C5	Dalton, C.B., <i>et al.</i> , "An Outbreak of Gastroenteritis and Fever Due to <i>Listeria Monocytogenes</i> in Milk," <i>N. Engl. J. Med.</i> , 336(2): 100-105 (1997).	
C6	Decedue, C.J., <i>et al.</i> , "Purification and Characterization of the Extracellular Proteinase of <i>Serratia Marcescens</i> ," <i>Biochim. et Biophysica Acta</i> , 569: 293-301 (1979).	
C7	Domann, E., <i>et al.</i> , "Molecular Cloning, Sequencing, and Identification of a Metalloprotease Gene from <i>Listeria monocytogenes</i> That Is Species Specific and Physically Linked to Listeriolysin Gene," <i>Infection and Immunity</i> , 59(1):65-72 (1991).	
C8	Engel, L.S., <i>et al.</i> , " <i>Pseudomonas aeruginosa</i> Protease IV Produces Corneal Damage and Contributes to Bacterial Virulence," <i>Invest. Ophthalmol. Vis. Sci.</i> , 39(3): 662-665 (1998).	
C9	Engels, W., and Kamps, M.A.F., "Secretion of staphylocoagulase by <i>Staphylococcus aureus</i> : the role of a cell-bound intermediate," <i>Antonie Van Leeuwenhoek</i> , 47(6): 509-524 (1981).	
C10	Ericsson, H., <i>et al.</i> , "An Outbreak of Listeriosis Suspected To Have Been Caused By Rainbow Trout," <i>J. Clin. Microbiol.</i> , 35(11): 2904-2907 (1997).	
C11	From the Centers for Disease Control and Prevention, "Update: Multistate Outbreak of Listeriosis--United States, 1998-1999," <i>JAMA</i> , 281(4): 317-318 (1999).	
C12	Glaser, P., <i>et al.</i> , "Comparative Genomics of <i>Listeria</i> Species," <i>Science</i> , 294: 849-852 (2001).	
C13	Gottesman, S., "Proteases and Their Targets in <i>Escherichia coli</i> ," <i>Annu. Rev. Genet.</i> , 30: 465-506 (1996).	

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C14	Hadziyannis, E., <i>et al.</i> , "Screening and confirmatory testing for extended spectrum $\beta$ -lactamases (ESBL) in <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> and <i>Klebsiella oxytoca</i> clinical isolates," <i>Diagnostic Microbiology and Infectious Disease</i> , 36: 113-117 (2000).	
C15	Häse, C.C. and Finkelstein, R.A., "Bacterial Extracellular Zinc-Containing Metalloproteases," <i>Microbiological Reviews</i> , 57(4): 823-837 (1993).	
C16	Keelan, S.L. and Flowers, R.S., "Multitest System for Biochemical Identification of <i>Salmonella</i> , <i>Escherichia coli</i> , and Other <i>Enterobacteriaceae</i> Isolated from Foods: Collaborative Study," <i>J. Assoc. Off. Anal. Chem.</i> , 71(5): 968-972 (1988).	
C17	Kennedy, E.P. and Scarborough, G.A., "Mechanism of Hydrolysis of O-Nitrophenyl- $\beta$ -Galactoside in <i>Staphylococcus Aureus</i> and Its Significance for Theories of Sugar Transport," <i>Proc. Natl. Acad. Sci. USA</i> , 58: 225-228 (1967).	
C18	Liu Y., <i>et al.</i> , "Use of a Fluorescence Plate Reader for Measuring Kinetic Parameters with Inner Filter Effect Correction," <i>Anal. Biochem.</i> , 267: 331-335 (1999).	
C19	Maeda, H., "Role of Microbial Proteases in Pathogenesis," <i>Microbiol. Immunol.</i> , 40(10): 685-699 (1996).	
C20	Marquis, H., <i>et al.</i> , "Proteolytic Pathways of Activation and Degradation of a Bacterial Phospholipase C during Intracellular Infection by <i>Listeria monocytogenes</i> ," <i>J. Cell Biol.</i> , 137(6): 1381-1392 (1997).	
C21	McAleese, F. M., <i>et al.</i> , "Loss of Clumping Factor B Fibrinogen Binding Activity by <i>Staphylococcus aureus</i> Involves Cessation of Transcription, Shedding and Cleavage by Metallaprotease," <i>J. Biol. Chem.</i> , 276(32): 29969-29978 (2001).	
C22	Molla, A., <i>et al.</i> , "Characterization of 73 kDa Thiol Protease from <i>Serratia Marcescens</i> and Its Effect on Plasma Proteins," <i>J. Biochem.</i> , 104: 616-621 (1988).	
C23	Molla, A., <i>et al.</i> , "Degradation of Protease Inhibitors, Immunoglobulins, and Other Serum Proteins by <i>Serratia</i> Protease and Its Toxicity to Fibroblasts in Culture," <i>Infection and Immunity</i> , 53(3): 522-529 (1986).	
C24	Nair, S. <i>et al.</i> , "ClpE, a Novel Member of the HSP100 Family, is Involved in Cell Division and Virulence of <i>Listeria monocytogenes</i> ," <i>Mol. Microbiol.</i> , 31(1): 185-196 (1999).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C25	Nelson, D., <i>et al.</i> , "Inactivation of $\alpha_1$ -Proteinase Inhibitor As a Broad Screen For Detecting Proteolytic Activities in Unknown Samples," <i>Analytical Biochemistry</i> , 260(2): 230-236 (1998).	
C26	O'Riordan, M., <i>et al.</i> , " <i>Listeria</i> Intracellular Growth and Virulence Require Host-Derived Lipic Acid," <i>Science</i> , 302: 462-464 (2003).	
C27	Okuno, K., <i>et al.</i> , "An analysis of target preferences of <i>Escherichia coli</i> outer-membrane endoprotease OmpT for use in therapeutic peptide production: efficient cleavage of substrates with basic amino acids at the P4 and P6 positions," <i>Biotechnology and Applied Biochemistry</i> , 36: 77-84 (2002).	
C28	Oshida, T., <i>et al.</i> , "A <i>Staphylococcus aureus</i> autolysin that has an N-acetylmuramoyl-L-alanine amidase domain and an endo- $\beta$ -N-acetylglucosaminidase domain: Cloning, sequence analysis, and characterization," <i>Proc. Natl. Acad. Sci. USA</i> , 92: 285-289 (1995).	
C29	Pallen, M.J. and Wren, B.W., "The HtrA family of serine proteases," <i>Mol. Microbiol.</i> , 26(2): 209-221 (1997).	
C30	Peterson, F. C., and Gettins, G. W., "Insight Into the Mechanism of Serpin-Proteinase Inhibition From 2D [ $^1\text{H}$ - $^{15}\text{N}$ ] NMR Studies of the 69 kDa $\alpha_1$ -Proteinase Inhibitor Pittsburgh-Trypsin Covalent Complex," <i>Biochemistry</i> , 40(21): 6284-6292 (2001).	
C31	Pioruńska-Stolzmann, M., <i>et al.</i> , "Serum Glycerol Ester Hydrolase Activity is Related to Zinc and Copper Concentrations in Atherosclerosis Obliterans and Aneurysm," <i>J. Trace Elem. Med. Biol.</i> , 12: 39-43 (1998).	
C32	Poyart, C., <i>et al.</i> , "The Zinc Metalloprotease of <i>Listeria monocytogenes</i> Is Required for Maturation of Phosphatidylcholine Phospholipase C: Direct Evidence Obtained by Gene Complementation," <i>Infect. and Immun.</i> , 61(4): 1576-1580 (1993).	
C33	Pütsep, K., <i>et al.</i> , "Germ-free and Colonized Mice Generate the Same Products from Enteric Prodefensins," <i>J. Biol. Chem.</i> , 275(51): 40478-40482 (2000).	
C34	Rice, K., <i>et al.</i> , "Description of <i>Staphylococcus</i> Serine Protease ( <i>ssp</i> ) Operon in <i>Staphylococcus Aureus</i> and Nonpolar Inactivation of <i>sspA</i> -Encoded Serine Protease," <i>Infection and Immunity</i> , 69(1): 159-169 (2001).	
C35	Rodriguez, M., <i>et al.</i> , "Evaluation of proteolytic activity of micro-organisms isolated from dry cured ham," <i>J. Appl. Microbiol.</i> , 85: 905-912 (1998).	

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	EXAMINER Not yet assigned		CONFIRMATION NO. 4672	GROUP Not yet assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C36	Rosenstein, R. and Götz, F., "Staphylococcal lipases: Biochemical and molecular characterization," <i>Biochimie</i> , 82: 1005-1014 (2000).	
C37	Salamone, P.R. and Wodzinski, R.J., "Production, purification and characterization of a 50-kDa extracellular metalloprotease from <i>Serratia marcescens</i> ," <i>Appl. Microbiol. Biotechnol.</i> , 48: 317-324 (1997).	
C38	Schwartz, M.A. and Luna, E.J., "Binding and Assembly of Actin Filaments by Plasma Membranes from <i>Dictyostelium discoideum</i> ," <i>J. Cell Biol.</i> , 102: 2067-2075 (1986).	
C39	Shikata, S., <i>et al.</i> , "Detection of Large COOH-Terminal Domains Processed From the Precursor of <i>Serratia marcescens</i> Serine Protease in the Outer Membrane of <i>Escherichia Coli</i> ," <i>J. Biochem.</i> , 111: 627-632 (1992).	
C40	Smith, G.A., <i>et al.</i> , "The Tandem Repeat Domain in the <i>Listeria monocytogenes</i> ActA Protein Controls the Rate of Actin-based Motility, the Percentage of Moving Bacteria, and the Localization of Vasodilator-stimulated Phosphoprotein and Profilin," <i>J. Cell Biol.</i> , 135(3): 647-660 (1996).	
C41	Sugai, M., <i>et al.</i> , "Identification of Endo- $\beta$ -N-Acetylglucosaminidase and N-Acetylmuramyl-L-Alanine Amidase as Cluster-Dispersing Enzymes in <i>Staphylococcus aureus</i> ," <i>J. Bacteriol.</i> , 177(6): 1491-1496 (1995).	
C42	Suter, S., and Chevallier, I., "Proteolytic Inactivation of $\alpha_1$ Proteinase Inhibitor in Infected Bronchial Secretions From Patients with Cystic Fibrosis," <i>European Respiratory Journal</i> , 4(1): 40-49 (1991).	
C43	Thompson, J.S., <i>et al.</i> , "Rapid Biochemical Test To Identify Verocytotoxin-Positive Strains of <i>Escherichia coli</i> Serotype O157," <i>J. Clin. Microbiol.</i> , 28(10): 2165-2168 (1990).	
C44	Ton-That, H., <i>et al.</i> , "Anchor Structure of Staphylococcal Surface Proteins," <i>J. Biol. Chem.</i> , 273(44): 29143-29149 (1998).	
C45	Trivett, T.L. and Meyer, E.A., "Citrate Cycle and Related Metabolism of <i>Listeria monocytogenes</i> ," <i>J. Bacteriol.</i> , 107(3): 770-779 (1971).	
C46	van Kampen, M.D., <i>et al.</i> , "Modifying the Substrate Specificity of Staphylococcal Lipases," <i>Biochem.</i> , 38: 9524-9532 (1999).	

EXAMINER	DATE CONSIDERED
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GROUP  
Not yet  
assigned